

REMARKS

Entry of the foregoing, reexamination and reconsideration of the above-identified application is respectfully requested.

Claims 13-37 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Claims 25, 28, 30, 35 and 36 are said to be included in the rejection since they depend from allegedly indefinite base claims 24, 26, 29 and 33. This rejection is respectfully traversed.

First, the phrase "number of hydrogen bonding sites" in claims 13, 24 and 29 is said to be a relative phrase, which number is not defined in the claim and a standard for determining the number is allegedly not provided. This assertion is in error. This phrase would be sufficiently clear to a person skilled in the art. A person skilled in the art would know what dextran's structure is and would know the number of hydrogen bonding sites present in the molecule. Dextran is a polymer of glucose units linked end to end, with a small degree of branching. Dextran generally has four hydrogen bonding sites, though it may have three if significant branching is present. ^{1/}Knowing the number of hydrogen bonding sites of dextran, one skilled in the art could readily look at the molecular structure of a different polysaccharide and determine whether it has the same number of hydrogen bonding sites.^{2/} For example, other glucose polymers, as well as polymers of other hexose sugars, would have a similar number of hydrogen bonding sites. One skilled in the art would recognize this based upon knowledge in the art at the time of the instant invention.

We note that this basis was previously used for a §112(2) rejection in the June 27, 2002 Official Action and was withdrawn, as it was not repeated in the December 23, 2003 Official Action.

Second, in claims 13, 14, 16, 18, 19, 20, 22-24, 26, 29, 32, 33 and 37, it is allegedly unclear whether “polysaccharide” is intended to be included as a dextran polysaccharide or any polysaccharide. “Polysaccharide” is also said to lack a definition for a plurality of molecular chains (of undisclosed length and composition). This assertion is in error.

Without reciting “dextran,” it should be clear that the claims include any polysaccharide, in addition to dextran polysaccharides. However, the claims require that the polysaccharide have a number of hydrogen bonding sites similar to dextran. This would require that the polysaccharide be similar to dextran in structure. For example, as stated *supra*, other glucose polymers or other hexose polymers would have similar bonding sites. (The polysaccharides encompassed by the claims would require such similarities so that the number of hydrogen bonding sites are the same. The polysaccharides of the claims are thus sufficiently clear.)

Third, claim 14 is said to lack antecedent basis for the phrase “in the manufacture of a medicament to improve mucus clearance.” The claim has been amended to correct this inadvertent error in including that language.

Fourth, the phrase “oligomers of galactose and fucose and the amino sugars glucosamine and galactosamine” in claims 15, 27 and 34 is allegedly a relative phrase,

which does not define the combination of galactose and fucose and amino sugars glucosamine and galactosamine or the type of linkages between them. This assertion is believed to be in error. The claims are sufficiently definite to a person skilled in the art. Further definition is not required.

As stated in the specification at page 8, lines 11-17, these moieties stereochemically complement the oligosaccharides in the respiratory tract mucins:

Other polysaccharides with a similar number of hydrogen bonding sites to dextran of the present invention or containing sugar moieties that stereochemically complement the oligosaccharide moieties native to the respiratory tract mucins, including oligomers of galactose and fucose and the amino sugars glucosamine and galactosamine are expected to compete for hydrogen bonding sites in the mucus gel, by forming complementary interaction with the oligosaccharide side chains of mucin macromolecules and thereby reduce the overall crosslink density of the mucus gel.

Page 8, lines 11-17.

(The particular combinations and linkages of the oligomers is not critical to the invention.) For the instant invention, the particular polysaccharide comprising oligomers of galactose and fucose and the amino sugars glucosamine and galactosamine need only “complement the oligosaccharide moieties native to the respiratory tract mucins,” as recited in claims 14, 26 and 33.

Fifth, in claims 17 and 21, the phrase “Ringer solution” is said not to be defined in the specification. “Ringer solution” is a well known solution, the name of which is an art-recognized term. More specifically, one skilled in the art would recognize “Ringer solution” as being a physiological aqueous solution containing 147.5 Na⁺ mmol/l, 156 mmol/l Cl⁻, 4 mmol/l K⁺ and 2.25 mmol/l Ca²⁺. See, e.g., De Sanctis et al, *Eur. Respir*

J. 6:76-82, 77 (1993). A search of U.S. Patents including this phrase in the specification and/or claims results in an enormous number of hits. "Ringer solution" or "Ringer's solution" is used in many patents and patent claims, without any description of the particular solution. *See, e.g.*, U.S. Patent No. 5,589,572, U.S. Patent No. 5,589,360 and U.S. Patent No. 6,284,772. This evidences that the phrase is so well known in the pharmaceutical art that a specific description of its make-up is not necessary in the instant application. No definition of "Ringer solution" is thus believed to be necessary in the specification.

In view of the above, withdrawal of the rejection under §112(2) is thus respectfully requested and believed to be in order.

In view of the above, all of the pending claims are believed to now be in condition for allowance.

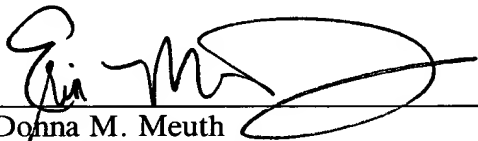
Further and favorable action in the form of Notice of Allowance is respectfully requested and believed to be in order.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (650) 622-2360 so that prosecution would be expedited.

Respectfully submitted,

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Date: July 18, 2003